Human Capacity Building in Africa – The BIRS Model

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With contributions from William Boogere, Portia Kampota, Oluwafunmike Mann, Andrew Mukungu, Denis Mwangomo,
The Challenge and the Vision

• People living in Africa face a heavy and wide-ranging burden of disease that takes an incalculable toll on social and economic development, as well as shortening life expectancy.

• The heavy reliance of Africa on imported medicine is further promoted by the lack of quality pharmaceutical industry and the lack of an adequate skilled workforce.

• Address this problem by enabling the manufacture of medicines in Africa for Africans by Africans.

• Initial efforts are focused on regulatory systems and capacity building efforts for Africans in the area of quality drug manufacturing.
A Decade of regulatory harmonization in Africa: Where are we? Where do we go from here?

A Model for Building Capacity: The BIRS Learning Environment

Academic

Collaboration & Professional Interaction

Regulatory

Industry

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The Purdue BIRS Curriculum

• Four Post-Baccalaureate Graduate Certificate Courses
  • Drug Development
  • Good Regulatory Practices
  • Quality Management Audits and Inspections
  • Molecular Basis of Manufacturing

• Core MS courses and competencies
  • Statistics
  • Leadership in BIRS
  • Medical Devices and Diagnostics
  • Foundations of Research in BIRS

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Backwards Design

• Collaborative with input from:
  • Academic faculty
  • Industry and Regulatory professionals
  • Students and Alumni


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Special Topics Graduate Courses

• BIRS Quality Culture Leadership
• Advanced Topics in Quality Manufacturing
• Innovation and Evidence-Based Natural Medicine
• Innovation in Biotechnology
• Global Drug Development with Considerations for Quality API Manufacturing and Regulation
• Overview of Regulatory Considerations for Drug Substance (API) Dossier Submission and Review
• Documents and Dialogues for Drug Development Registration

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Outcomes

Fig 1. Distribution of African countries represented in the BIRS program

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Fig 2. Participants in different levels of training

Fig 3. Graduates of first masters class

Outcomes

<table>
<thead>
<tr>
<th>Level of Training</th>
<th>Number of Certificates Awarded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certificate Graduate 2008 - Present</td>
<td>86</td>
</tr>
<tr>
<td>Masters Graduate 2017-2018</td>
<td>44</td>
</tr>
<tr>
<td>Masters Intake to Graduate in 2020</td>
<td>53</td>
</tr>
<tr>
<td>PhD Intake 2018</td>
<td>2</td>
</tr>
</tbody>
</table>
Impact of Directed Projects

- Alumni have improved manufacturing and regulatory systems in their places of practice through innovative directed projects – examples
  - Central drug control laboratory of NAFDAC
  - Tanzanian FDA
  - Coopers K-Brands limited (Kenya)
  - Regal Pharmaceuticals Limited (Kenya)
  - Brentec Vaccines (Uganda)
  - Emzor Pharmaceuticals (Nigeria)
“The BIRS program provided a network of experts, intra-Africa and internationally, where we continuously share ideas. Most importantly, priceless Leadership skills that will enable us to lead the African Pharmaceutical Industry to be able to sustainably make quality medicines for Africans and beyond”

Portia Kampota
Varichem Pharmaceuticals
Zimbabwe
“As a dossier assessor and GMP inspector, I found the program tailored to my needs, especially the courses on quality and manufacturing. Currently 16 TMDA staff have been or are participants in this program. This has made an impact on TMDA. We always share the knowledge gained from this program with our colleagues”

Denis Mwangomo
TMDA
“I have gradually but surely been transformed, everything I have done for more than 10 years! began to add up. I became knowledgeable in regulatory science with the up-to-date information provided during on and off-site lectures, group work, role plays, a better team player; a leader; part of the strong network of leaders in medicines manufacture and regulation in Africa.”

Oluwafunmike Mann
WAHO
“The Content from this course is unique as it enables me to understand what regulators are looking for both during audits and dossier review. I have had an opportunity to relate with regulators across Africa and Europe. This is a great opportunity for me to keep abreast with current regulatory expectations across the world. Part of the lessons I have learnt is to freely share the knowledge I have gained. My lecturers call it ‘paying forward’.”

Andrew Mukungu
CIPLA Chemical Industries LTD
Uganda
Impact: Testimonies From Alumni and Students

• “This course has been very instrumental in improving the quality of GMP Inspections, CTD Dossier Evaluation and Laboratory Activities

• The course furnishes us with a lot of essential knowledge but the work environment in Uganda only appreciates knowledge backed up with academic documents. The graduate status adds credibility to the holder.”

Boogere William Wakaalo
Senior Analyst
National Drug Authority, Uganda.
“Safe, quality and effective medicines for Africans is my passion. The BIRS program has helped me to chart a course to realizing that passion. Through my masters’ directed project I was able to implement quality management systems in the sample handling process of the Central Drug Control Laboratory that was a linchpin in the subsequent accreditation of the laboratory. I am an emerging leader in the regulatory palance”

Abigail Ekeigwe
NAFDAC
Conclusion

• The BIRS program is breaking the cycle of insufficient human capacity building in Africa.
Thank you
Q&A

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